

# Informed Prostate Cancer Support Group Inc.



"A 501 C 3 CORPORATION ID # 54-2141691"



## **AUGUST 2022 NEWSLETTER**

P.O. Box 420142 San Diego, CA 92142 Phone: 619-890-8447 Web: http://ipcsg.org



Volume 15 Issue 08

- Next Meeting Saturday, August 20, 2022 IPCSG— Next-Generation Cancer Treatment Using a Nontoxic Metabolic Therapy — Live-Stream Event, 10:00am PT.
- Robert Hoffman, Professor Emeritus in the UCSD Dept. Of Surgery, will teach us from his fifty years
  of research, "How to Starve Cancer Naturally." He will be joined by Mark Simon, CN, of the Nutritional Oncology Research Institute. Dr. Hoffman's recommendations focus on starving cancer by limiting its access to the amino acid Methionine through diet and a methioninase supplement. His website
  is <a href="mailto:howtostarvecancernaturally.com">howtostarvecancernaturally.com</a>. Email: meishale@gmail.com.
- Due to COVID-19, no in-person meetings at the Sanford Burnham Prebys Medical Discovery Institute
  will take place until further notice. This meeting will be live-streamed and will also be available on
  DVD.
- For links to further Reading: <a href="https://ipcsg.blogspot.com/">https://ipcsg.blogspot.com/</a>
- If you have Comments, Ideas and Questions, email to Newsletter@ipcsg.org
- If you would like some copies of our new brochure by mail for distribution to your friends or physicians, please send email to bill@ipcsg.org or call Bill at (619) 591-8670

July 2022 Informed Prostate Cancer Support Group Meeting - Member Round Table Summary by Bill Lewis

I. **Pat Miller** – Had a PSA of 3-4 in July 2016. When retested a year later, the PSA was up to 14. A standard 12-core biopsy showed Gleason 9 disease. In early 2018, he had 25 IMRT radiation doses, plus six SBRT doses to his L3 lumbar & right femur. In April 2019 he started Zytiga (alone) at 250 mg per day. Side effects were hot flashes & sweats. His PSA nadir was <0.06. In March 2021, he stopped the Zytiga, and a month later, his PSA had jumped to 9.5. So he went back on Zytiga until now, but at 1000 mg per day. Then late last year, when PSMA scanning became available, it showed a pubic bone tumor; Pat got 6 more SBRT treatments. This year, his PSA rose a bit, then has hovered at about 2-3. His wife of 51 years passed away last November, after four rounds of chemo for small cell carcinoma. Based on her suffering, he's not likely to ever accept chemotherapy.

Pat has no special diet, but watches his weight gain, limiting it to 10 lbs. He does regular weightlifting etc., 3-4 days weekly. His strength and energy are down somewhat, due to testosterone suppression.

Looking Forward: He plans to get a PSMA scan again, to search and destroy – to stay ahead of the dis-

ease. Will be deciding whether to stay on Zytiga, or change. He would like testosterone replacement therapy, if only it would not cause his cancer to grow.

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Page I Disclaimer 8/16/2022



#### **Organization**

a 501c3 non-profit organization - all positions are performed gratis

#### **Officers**

Bill Lewis President

Additional Directors

Gene Van Vleet Aaron Lamb Bill Manning

# Honorary Directors Dr. Dick Gilbert

Judge Robert Coates

Past President -Lyle Larosh

Aaron Lamb, .......Facilitator

Bill Manning, ......Videographer

John Tassi, ......Webmaster

Bill Bailey, .....Librarian

# **NEWSLETTER Table of Contents**

Jim Kilduff, .....Greeter

Aaron Lamb, ..... Meeting Set-up

Stephen Pendergast ...... Editor

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# PROSTATE CANCER—2 WORDS, NOT A SENTENCE What We Are About

Our Group offers the complete spectrum of information on prevention and treatment. We provide a forum where you can get all your questions answered in one place by men that have lived through the experience. Prostate cancer is very personal. Our goal is to make you more aware of your options before you begin a treatment that has serious side effects that were not properly explained. Impotence, incontinence, and a high rate of recurrence are very common side effects and may be for life. Men who are newly diagnosed with PCa are often overwhelmed by the frightening magnitude of their condition. Networking with our members will help identify what options are best suited for your life style.

#### **Meeting Video DVD's**

DVD's of our meetings are available for purchase on our website at https://ipcsg.org/purchase-dvds and are generally available by the next meeting date.

#### Join the IPCSG TEAM

If you consider the IPCSG to be valuable in your cancer journey, realize that we need people to step up and HELP. Call **President** Bill Lewis @ (619) 591-8670; or **Director** Gene Van Vleet @ 619-890-8447.

#### From the Editor

Due to COVID-19, no in-person meetings will be held until further notice. We will continue to post and distribute the newsletter in the interim. Our speaker this month will be broadcast via the IPCSG website at https://ipcsg.org/live-stream and can be watched by scrolling down and clicking on the "WATCH THE PRESENTATION" button. The broadcast will begin approximately 10 minutes before to the listed start time.

#### In this issue:

Bill Lewis produced a summary of the last stream video, followed by a notice of source of to help with medical bills and medication.

#### **Articles of Interest:**

- I. Drugs or Active Surveillance for Low-Risk Prostate Cancer?-60% go with AS. Is oral ARI hormone therapy ok
- Bavdegalutamide Showcases Early Activity in Metastatic Castration-Resistant Prostate Cancer- Androgen Recoptor Degrader may help MCRCa patients
- 3. Prostate Cancer Treatment May Raise Heart Risks- patients with heart problems may be at risk with ADT.
- 4. FDA approves darolutamide for CRMPCa (Nubeqa, Bayer HealthCare Pharmaceuticals Inc.) tablets.

2. **Mike Dibitetto** – Age 71, and involved with 3 restaurants, golfing, and grandkids. He was diagnosed in August/September 2019 with Stage 4 PCa including iliac and aortic lymph nodes near kidneys – PSA = 43, Gleason = 9. There were 12 biopsy cores; 11 positive, mostly Gleason 7, but one = 9. 40-95% of each core had cancer. He had Casodex briefly as he had a 3-month Eligard (Lupron equivalent) shot, then went on Zytiga + prednisone and left off the Eligard. The node tumors were found with an Axumin scan. He had a very negative experience with a pessimistic Mayo clinic doctor, but better with an MD Anderson consultation; found a good local Radiation Oncologist. She gave him nine weeks of radiation in March/April 2020, with the SpaceOAR gel. A subsequent Axumin scan showed no tumors left; PSA = 0.05.

Along the way, Mike had numerous difficulties. He has suffered with a bad back, leg DVT, a bleeding polyp, skin cancer, dry mouth, a shattered ankle followed by dehydration, an episode of pneumonia, and a severe reaction to going off prednisone (which he is back on). Also the covid pandemic affected his restaurant businesses, but they survived.

In April of this year, his PSA rose to 1.4. He added Eligard again, as monthly shots, and this pushed his PSA down to 0.6. At the meeting, he reported the results of a PSMA Pylarify scan that was done on July 5<sup>th</sup>.

3. **Bob Stacy**, now 59 years old. After tracking his PSA for 10 years (working as a firefighter and knowing his father and uncle had (non-fatal) prostate cancer), he was diagnosed in May 2019 with a 12-core biopsy, which showed Gleason 3+4. Highest PSA was 5.9. He then did research for three months and settled on proton therapy with Dr. Rossi (28 sessions). Side effects were a bit of pain with urination, and urgency, starting 10 days into the treatments and lasting 2 weeks beyond. Also some fatigue. He continued physical therapy, exercises with weights, uses his road bike and plays lots of ball.

His PSA went as low as 1.2, then went back to 1.4. Soon after, he had pain on urination, and had a kidney stone removed. A bit later, pain again, and another kidney stone removed. He asked for an MRI, which found a suspicious spot on his sacrum. Possible metastatic cancer! A bone scan showed the same spot. A PSMA scan showed – you guessed it – the same spot on his sacrum. A bone biopsy was recommended, and after consulting many friends, including members of the IPCSG, Bob chose to get the biopsy. Negative for cancer!

At the time of the talk, he was still having pain on urination, with a PSA of I.7. Supplements being taken: Fish oil, Vitamin D, probiotics, and FlowMax. Aaron Lamb noted that he got help from Celebrex, which is said to be good for idiopathic (unknown-cause) pain. Also, a relative solved his repetitive kidney stones with hernia surgery. Mike D. noted that in addition to FlowMax, his doctor gives him Myrbetriq, which reduces the need for frequent urination at night.

Since the meeting, Bob has had a third kidney stone removed, and has been able to urinate without pain. His doctor said he believes that the radiation treatments he has had have somehow made him more susceptible to kidney stones.

#### Questions, comments, and answers:

Info on signing up for Medicare and supplemental insurance was requested. We will put information in the October newsletter, to match up with the annual signup / change period. We can also provide info in response to calls to the hotline numbers for Gene or Bill.

Pat Miller asked about the value of Gleason scores after treatment. https://pubmed.ncbi.nlm.nih.gov/11062366/ shows that Gleason scores rise if hormone therapy is given before radical prostatectomy. <a href="https://www.inspire.com/groups/zero-prostate-cancer/discussion/post-radiation-therapy-gleason-scores-unreliable/">https://www.inspire.com/groups/zero-prostate-cancer/discussion/post-radiation-therapy-gleason-scores-unreliable/</a> includes a statement from <a href="https://www.bostwicklaboratories.com/global/physicians/medical-">https://www.bostwicklaboratories.com/global/physicians/medical-</a>

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<u>library/articles/gleason-grading.aspx</u> that indicates that radiation also causes the Gleason score to rise and to be unreliable.

Bob August wants a PSMA scan but is getting insurance company grief. He's at Scripps. A member noted that the cash price is \$4600 at IHS (Imaging Healthcare Specialists). Bob also asked about PSMA theranostics, and was referred to the IPCSG talk in July by a Telix Pharmaceuticals representative.

Albert Schafer made several interesting comments. Will join us again in November. Had proton radiation paid for by insurance after "asking for less side effects." Mentioned cryotherapy, and says it is available at UCSD.

William Sandberg asked about expected side effects with SBRT, with SpaceOAR. Several were mentioned – see the video.

New focal therapies include the use of dc current, per Aaron. Somewhere in the Midwest.

Digestive enzymes, per Aaron, helped when he had diarrhea from radiation treatments. "Pure encapsulations digestive enzymes ultra," from Amazon, taken on occasion. 90 capsules for \$30.

PSMA theranostics discussion – see the video.

Urolift was mentioned. They pin back the prostate to permit easier urination.

A member noted that his proton therapy was covered by Medicare/UHC (United Healthcare).

Douglas asked about emotion therapy – Aaron recommended that he go for it, as it was very helpful to him.

The Body Keeps Score – book recommended by Albert Schafer.

Mike Dibitetto said that a lady with breast cancer in her lung got a PSMA test that showed the lung spots.

Phil Young re PSA vs. covid: His PSA was 0.8 to 1.4 in 30 years, then to 2.1 in 1 year after covid. Possibility of prostate "leaking" more due to virus. Another member said two jabs + a booster seemed to really raise his PSA. His PSA of 14 (which previously was stable) went to 25. Rumors about that from others. Got PSMA, but no results yet. Bob August had a PSA slightly down after positive test for covid.

See the video online for the talk and slides: <a href="https://youtu.be/Qef9d63qvwU">https://youtu.be/Qef9d63qvwU</a>

A dvd of the roundtable discussion will be available for purchase from the IPCSG by the time of next month's meeting. Order online from the IPCSG.org website.

#### A Source of Charitable Financial Aid

**FundFinder** is a service from the Patient Advocate Network foundation. If you go to <a href="https://fundfinder.panfoundation.org/">https://fundfinder.panfoundation.org/</a> and click "Sign Up," you will receive email notices and optionally, text messages, to let you know when one of many charitable organizations has funds available to you for your specific cancer interest, to help with copays for a wide variety of treatments. Among the funds, besides PAN foundation itself, there can be notices from CancerCare, Healthwell, Patient Advocate Foundation, The Assistance Fund, and perhaps others. I have personally received assistance from several of these funds. Usually, a low current income is the only requirement. It's helpful to sign up for the text notifications, because funds are allocated (for a set amount, or for a year) on a first-come basis. So quick action is of the essence! -- Bill Lewis

#### **WEBINAR**

All - PLEASE REGISTER for NASPCC's free I-hour WEBINAR (for patients and Families) with Dr. Eric Klein of the Cleveland Clinic (currently on a year sabbatical at Stanford University), who will speak on "INNOVATIONS IN PROSTATE CANCER" on Thursday, September 8, at 7:00 pm EASTERN. Here is how to register directly on our website:

https://register.gotowebinar.com/register/7453158739857219086

#### **Articles of Interest**

## **Drugs or Active Surveillance for Low-Risk Prostate Cancer?**

#### medscape.com

Howard Wolinsky

In the past, even patients with low-risk prostate cancer would often be treated with surgery or radiotherapy, as men opted for an aggressive approach to get rid of the cancer, despite potentially serious side effects from the treatment.

But recent years have seen a marked move away from immediate treatment. About <u>60% of patients</u> with <u>low-risk prostate cancer</u> now forgo treatment, opting instead for a regime of active surveillance (AS).

The <u>American Urological Association</u> is urging that the proportion rise still further, to at least 80% in the near future, as emerging research underscores the slow-growing and even nonmalignant nature of most low-risk prostate tumors.

However, some researchers, backed by pharmaceutical companies, appear to be exploring a new treatment approach for these patients.

Rather than advocate only AS for this group, they are looking to the use of oral androgen receptor inhibitors (ARIs), a class of potent and expensive hormonal therapies that include apalutamide, enzalutamide, and darolutamide. So far, these drugs have been approved only for use in the treatment of advanced prostate cancer. Wholesale prices for these drugs exceed \$150,000 annually and can reach well into six figures.

The prospect of using medication for patients with less aggressive tumors has alarmed some cancer experts.

Christopher Booth, MD, of the Division of Cancer Care and Epidemiology, Queen's University Cancer Research Institute, Kingston, Ontario, Canada, said he suspects drug companies may try to cash in on the growing market of patients with early, localized prostate cancer that they previously ignored.

"Uptake of active surveillance over the past two decades has been a huge advance for patients with early-stage prostate cancer, as it allowed us to deescalate care, reduce side effects, and preserve good outcomes," Booth told Medscape Medical News.

I cannot see how this represents an important advance for patients. I worry we are taking a step backward if clinicians begin to adopt this approach over true active surveillance. Dr Christopher Booth

Regarding the prescribing of ARIs to men who don't need them, Booth said, "I cannot see how this represents an important advance for patients. I worry we are taking a step backward if clinicians begin to adopt this approach over true active surveillance."

Channing Paller, MD, a medical oncologist at Johns Hopkins University, Baltimore, said she doesn't think she'd ever recommend hormonal therapy to any patient with low- or favorable intermediate—risk prostate cancer.

"I think the patient will likely do well anyway and still has options for therapy if there is clinical progression," Paller said. "I am concerned about adding in hormonal therapy, even oral agents, because it just gives individuals side effects for not clinically significant endpoints."

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# Bavdegalutamide Showcases Early Activity in Metastatic Castration-Resistant Prostate Cancer

#### onclive.com

Kristi Rosa

The novel androgen receptor PROTAC degrader, bavdegalutamide, was found to be clinically active and tolerable with manageable adverse effects in patients with metastatic castration-resistant prostate cancer.

The novel androgen receptor (AR) PROTAC degrader, bavdegalutamide (ARV-110), was found to be clinically active and tolerable with manageable adverse effects (AEs) in patients with metastatic castration-resistant prostate cancer (mCRPC) following 1 to 2 prior novel hormonal drugs, according to data from the phase 1/2 ARDENT trial (NCT03888612).

Results, which were presented during the **2022 Genitourinary Cancers Symposium**, showed that 46% of patients whose tumors harbored AR T878X/H875Y mutations (n = 28) experienced prostate-specific antigen (PSA) declines of 50% or higher (PSA50); 57% of these patients had PSA declines of 30% or higher (PSA30). Notably, PSA declines of at least 50% were also noted in those whose tumors did not harbor these mutations.

"Patients in the less pretreated subgroup, based on clinical history, and those in the more pretreated biomarker-defined subgroups had tumors with similar non-AR molecular profiles," lead study author Xin Gao, MD, of Massachusetts General Hospital, said in a presentation on the data. "Bavdegalutamide merits further investigation in patients with mCRPC."

The novel, oral PROTAC protein degrader was designed to target wild-type AR and clinically relevant mutants. In a phase I dose-escalation study of the agent in patients with mCRPC who previously received at least 2 therapies, including abiraterone acetate (Zytiga) and/or enzalutamide (Erleada), an exposure/activity relationship was observed in heavily pretreated patients.

Moreover, a PSA50 rate of 40% was reported in a subset of patients whose tumors harbored AR T878X/H875Y mutations (n = 5). Based on the safety, pharmacokinetic (PK), and efficacy data, investigators selected a once-daily dose of 420 mg as the recommended phase 2 dose (RP2D).

The phase 2 expansion trial enrolled those with confirmed metastatic CRPC and experienced disease progression on, or since, their most recent therapy received, as well as 2 or higher rising PSA values (≥2 ng/mL).

The biomarker-defined subgroups included those with AR T878A/S and/or H875Y; wild-type AR or AR alterations other than T878A/S, H875Y, L702H, AR-V7; and AR L702H or AR-V7 (co-occurring T878X/H875Y included). These patients previously received I to 2 hormonal agents, and at least I prior chemotherapy each for castration-sensitive disease and CRPC. There was also a clinically defined, biomarker agnostic subgroup of less pretreated patients who received I prior novel hormonal agent, but no prior chemotherapy.

Bavdegalutamide was given at a starting dose of 420 mg once daily. Notably, dose reductions and interruptions were allowed for those who needed them due to toxicity.

The primary end points of the trial included PSA response rate, RECIST response rate, progression-free survival (PFS) and radiographic PFS. Key secondary end points comprised duration of response, overall survival, safety and laboratory abnormalities, and PK parameters.

The analysis presented at the meeting includes complete findings from the phase I portion of the trial and interim data from the phase 2 portion of the research. The data cutoff date for the analysis was December 20, 2021.

Among the 124 patients included in the phase 2 portion of the trial, the median age was 74 years (range, 48-91), 50% had an ECOG performance status of 1, 31% had visceral disease, and the median

number of prior lines of therapy received was 4 (range, I-II). All patients received a prior novel hormonal agent; 64% of patients had prior abiraterone, 75% had prior enzalutamide, and 39% previously received both agents. Thirty-one percent of patients previously received chemotherapy.

Additional data showed that 2 of 7 patients with tumors harboring AR T878X/H875Y mutations had confirmed RECIST partial responses to treatment.

Moreover, PSA declines of 50% or higher were observed across all subsets of patients analyzed in the ARDENT trial. Eleven percent of patients who had wild-type AR or AR alterations other than T878A/S, H875Y, L702H, AR-V7 (n = 44) experienced PSA50; 20% of these patients had PSA30. Four percent of patients with AR L702H or AR-V7 mutations (n = 25) had PSA50; 20% of these patients had PSA30. Lastly, 22% of patients in the less pretreated subset (n = 27) had PSA50; 26% of these patients had PSA30.

Regarding safety, 83% of patients experienced treatment-related AEs (TRAEs). The most common TRAEs included nausea (48%), fatigue (36%), vomiting (26%), decreased appetite (25%), diarrhea (20%), alopecia (14%), aspartate aminotransferase increased (12%), weight decreased (12%), and anemia (11%). The most common grade 3 toxicities were anemia (5%) and diarrhea (2%).

Eight percent of patients who received bavdegalutamide at the RP2D experienced TRAEs that led to dose reductions, and 9% had TRAEs that resulted in treatment discontinuation.

#### Reference

Gao X, Burris HA, Vuky J, et al. Phase 1/2 study of ARV-110, an androgen receptor (AR) PROTAC degrader, in metastatic castration-resistant prostate cancer. *J Clin Oncol.* 2022;40(suppl 6):17. doi:10.1200/JCO.2022.40.6\_suppl.017

## Prostate Cancer Treatment May Raise Heart Risks

#### medicinenet.com

By Cara Murez HealthDay Reporter

WEDNESDAY, July 27, 2022 (HealthDay News)

Hormone therapy is a common treatment option for prostate cancer, but it may increase the risk of death from heart disease, especially in older men, a new study finds.

Dr. William Dahut, a <u>prostate cancer</u> researcher and chief scientific officer for the American <u>Cancer</u> Society, said the study from Lithuania provides more evidence that starting hormonal therapy requires careful thought, particularly if the patient is over 70 and has <u>heart disease</u>.

"There are some cases where it's clear men need hormonal therapy," Dahut said, citing <u>prostate cancer</u> that has spread. "But oftentimes it's used for patients that are newly diagnosed, that are receiving <u>radiation</u> or with men that have a rising PSA [<u>prostate specific antigen</u>] without <u>cancer</u> that we can see, something called biochemical recurrence."

In terms of <u>biochemical recurrence</u>, "it needs to be looked at very carefully because there's much less data there that hormonal therapy will have an impact on how long patients live from prostate <u>cancer</u>," said Dahut, who was not involved in the study.

Doctors should consider whether to use hormonal therapy or how long to use it on a case-by-case basis, Dahut noted.

Hormone therapy, or androgen deprivation therapy, is considered a mainstay treatment for patients who have either high-risk localized prostate cancer or advanced cancer that has metastasized.

For the study, researchers used data from a Lithuanian <u>cancer</u> registry for patients ages 40 to 79 who had <u>prostate cancer</u> diagnoses between 2012 and 2016.

About 3,800 men received hormone-lowering drugs and more than 9,500 did not. In a follow-up roughly five years later, the researchers looked at overall death from heart disease and stroke.

They found a twofold increase in the risk of death from <u>cardiovascular disease</u> in men who had hormone therapy. They also found a higher risk of <u>heart</u> disease-related death from the second year onward

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after diagnosis.

Those who were 70 to 79 and had hormone therapy had an almost fivefold higher risk, according to the study published July 26 in the journal <u>The Aging Male</u>.

When looking at specific types of disease, the team found a 42% higher risk of dying from stroke and a 70% higher risk of dying from coronary heart disease in men who had hormone therapy.

"Prostate <u>cancer</u> is typically diagnosed in older men, over 65 years or older -- and many of them will have already been diagnosed with <u>cardiovascular disease</u>," lead author Justinas Jonusas, of the National Cancer Institute in Vilnius, Lithuania, said in a journal news release.

The results suggest clinicians should screen older prostate cancer patients for <u>heart disease</u> and related risk factors, Jonusas and other experts said.

Previous studies have not come to a clear conclusion about a link between the therapy and cardiovascular risk, the study noted. Moreover, the current observational study can't establish a direct cause-andeffect relationship.

Still, what can doctors do to treat one serious disease while not exacerbating another? It may depend on the patient and his specific risks.

Men who are diagnosed with localized disease -- cancer that hasn't spread -- could undergo surgery, in which case they might not receive hormonal therapy, Dahut said. Those who opt for <u>radiation</u> may be able to do that without hormonal therapy or have a very short course of hormonal therapy.

"There is research ongoing now to be able to better differentiate which patients actually need hormonal therapy who are receiving radiation," Dahut noted.

In general, doctors and patients will need to assess potential risks and benefits, Dahut said.

Hormone therapy is not the only cancer treatment that can increase cardiovascular risk, said Dr. Katelyn Atkins, who specializes in cardiac radiation <u>oncology</u> at Cedars-Sinai Cancer Institute in Los Angeles.

"We think about all these different cancer therapies. They can all have a risk on the <u>cardiovascular system</u> from directly, like radiation, indirectly from hormonal therapy, but also immunotherapies, cytotoxic chemotherapies. They all work differently, but they can have overlapping and separate and distinct risks on the <u>heart</u> and the whole <u>cardiovascular system</u>," Atkins said.

Often, doctors will need to treat patients for their cancer despite heart risks, but after ensuring they're connected with a cardiologist to receive care.

It's important to understand that there are going to be some subgroups of patients that are at particularly high risk, Atkins added.

Those patients may need more stringent goals for their <u>blood pressure</u> and <u>cholesterol</u> numbers, she said.

Dahut said the medical community needs tools to better predict for whom hormonal therapy can be trivial and for whom it may be lifesaving.

"If we can do research to differentiate those populations, it will make the discussions much easier for patients and their physicians," Dahut said.

#### More information

The U.S. National Cancer Institute has more on hormone therapy for prostate cancer.

# FDA approves darolutamide tablets for metastatic hormone-sensitive pro fda.gov

On August 5, 2022, the Food and Drug Administration approved <u>darolutamide</u> (<u>Nubeqa, Bayer</u> <u>HealthCare Pharmaceuticals Inc.</u>) tablets in combination with docetaxel for adult patients with metastatic

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hormone-sensitive prostate cancer (mHSPC).

The primary efficacy measure was overall survival (OS). Time-to-pain progression was an additional efficacy measure. Median OS was not reached (NR) (95% CI: NR, NR) in the darolutamide plus docetaxel arm and 48.9 months (95% CI: 44.4, NR) in docetaxel plus placebo arm (HR 0.68; 95% CI: 0.57, 0.80; p<0.0001). Treatment with darolutamide and docetaxel resulted in a statistically significant delay in time-to-pain progression (HR 0.79; 95% CI: 0.66, 0.95; I-sided p=0.006).

The most common adverse reactions were constipation, decreased appetite, rash, hemorrhage, increased weight, and hypertension. The most common laboratory test abnormalities (≥30%) were anemia, hyperglycemia, decreased lymphocyte count, decreased neutrophil count, increased AST, increased ALT, and hypocalcemia.

The recommended darolutamide dose for mHSPC is 600 mg (two 300 mg tablets) taken orally, twice daily, with food until unacceptable toxicity or disease progression. Docetaxel, 75 mg/m2 intravenously is administered every 3 weeks for up to 6 cycles. The first dose of docetaxel should be administered within 6 weeks after the start of darolutamide treatment. https://www.nubeqa-us.com/

## On the Lighter Side













"I tell ya, work has gotten to be so much more fun since we hung that rubber spider in there."

"Male, 38, still living with his parents. They asked us to keep him overnight, so they could change the locks."

#### **NETWORKING**

Please help us in our outreach efforts. Our speakers bureau consisting of Gene Van Vleet is available to speak to organizations of which you might be a member. Contact Gene 619-890-8447 or gene@ipcsg.org or Bill (619) 591-8670 (bill@ipcsg.org) to coordinate.

Member John Tassi is the webmaster of our website and welcomes any suggestions to make our website simple and easy to navigate. Check out the Personal Experiences page and send us your story. Go to: https://ipcsg.org/personal-experience

Our brochure provides the group philosophy and explains our goals. Copies may be obtained by mail or email on request. Please pass them along to friends and contacts.

### **FINANCES**

We want to thank those of you who have made <u>special donations</u> to IPCSG. Remember that your gifts are <u>tax deductible</u> because we are a 501(c)(3) non-profit organization.

We again are reminding our members and friends to consider giving a large financial contribution to the IP-CSG. This can include estate giving as well as giving in memory of a loved one. You can also have a distribution from your IRA made to our account. We need your support. We will, in turn, make contributions from our group to Prostate Cancer researchers and other groups as appropriate for a non-profit organization. Our group ID number is 54-2141691. Corporate donors are welcome!



While our monthly meetings are suspended, we still have continuing needs, but no monthly collection. If you have the internet you can contribute easily by going to our website, <a href="http://ipcsg.org">http://ipcsg.org</a> and clicking on "Donate" Follow the instructions on that page. OR just mail a check to: IPCSG, P. O. Box 420142, San Diego CA\_92142